

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

<b>In re Application of:</b>	<b>Tracee Eidenschink</b>
<b>Application No.:</b>	<b>10/663641</b>
<b>Filed:</b>	<b>September 17, 2003</b>
<b>For:</b>	<b>BALLOON ASSEMBLY WITH A TORQUE</b>
<b>Examiner:</b>	<b>Catherine Witzczak</b>
<b>Group Art Unit:</b>	<b>1904</b>

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**Docket No.: S63.2B-11019-US01**

**Request for Reconsideration of Patent Term Adjustment, 37 CFR 1.705**

The patentee hereby requests reconsideration, under 35 USC 154(d), of the Determination of Patent Term Adjustment (PTA) made by the Director as indicated on the Issue Notification and on the cover page of US 7597702, issued 10/6/2009, copies of which are attached hereto. Applicant also requests that consideration of this petition be held in abeyance until *Wyeth v. Dudas*, 88 USPQ2d 1538 (D.D.C. 2008), currently on appeal, is decided.

**Determination of Patent Term Adjustment**

As indicated on the face of the patent and on the Issue Notification, the adjustment to patent term is 1104 days. Also attached is the PAIR record showing the basis for this determination, which is believed to be incorrect.

The above referenced application was filed on 9/17/2003 and so is entitled to the benefit of the current version of 35 U.S.C. § 154. The PTA determination fails to follow the calculation method required by law as determined in *Wyeth v. Dudas*, 88 USPQ2d 1538 (D.D.C. 2008), currently on appeal to the Federal Circuit, which is controlling law for the issues presented herein.

This Application for PTA constitutes a request that the patent term adjustment be made in accordance with the determination method described in the *Wyeth* case.

- (1) This request is accompanied by the fee set forth in 37 CFR § 1.18(e).
- (2) This request is being timely filed by 12/07/2009. The patent issued 10/06/2009 and

the two month date for petitioning the commissioner falls on Sunday, 12/06/2009. Consequently, the due date is 12/07/2009. This request could not have been filed prior to the issuance of the patent as the "three year" delay days could not have been determined until the issuance date. To that end, Petitioner notes that a petition filed by this law firm prior to the issue date, in application **10/732983**, was held in abeyance pending issuance of the patent in a decision in which the Office stated:

As the instant application for patent term adjustment requests reconsideration of the patent term adjustment as it relates to the Office's failure to issue the patent within 3 years of the filing date, a decision is being **held in abeyance** until after the actual patent date. Knowledge of the actual date the patent issues is required to calculate the amount, if any, of additional patent term patentee is entitled to for Office failure to issue the patent within 3 years. See § 1.703(b).

and further:

Rather than file the request for reconsideration of Patent Term Adjustment at the time of the mailing of the notice of allowance, applicant is advised that they may wait until the time of the issuance of the patent and file a request for reconsideration of the patent term pursuant to 37 CFR 1.705(d). The USPTO notes that it does not calculate the amount of time earned pursuant to 37 CFR 1.702(b) until the time of the issuance of the patent and accordingly, the Office will consider any request for reconsideration of the patent term adjustment due to an error in the calculation of 37 CFR 1.702(b) to be timely if the request for reconsideration is filed within two months of the issuance of the patent.

Therefore it is clear that this request is timely.

(3) Statement of the facts involved:

- (i) The correct patent term adjustment and the basis under 37 CFR § 1.702 for the adjustment is as follows:

USPTO delay days to the issuance of the first Office Action as indicated on PAIR	+ 1052
Non-overlapping three year days	+ <u>732</u>
Total USPTO delay days	1784
Applicant's delay days as indicated on PAIR	- 11
Correct Adjustment	= <b>1773</b>

- (ii) The relevant dates as specified in §§ 1.703(a) through (e) for which an adjustment is sought and the adjustment as specified in § 1.703(f) to which the patent is entitled are explained as follows:

The Office calculation of 1115 days fails to properly include all of the USPTO delay days. As *Wyeth* establishes, this is improper. No time was consumed by an interference proceeding under 35 U.S.C. 135(a); no time was consumed by the imposition of a secrecy order under 35 U.S.C. 181; the patent issued or the first RCE was filed after the 3 year date. An Appeal to the Board of Patent Appeals and Interferences was filed which resulted in the Examiner re-opening prosecution. A period of 219 days was consumed between Applicant's filing of the notice of appeal on 07/02/2008 and the mailing date of the Non-Final Rejection reopening prosecution (02/06/2009). See 37 CFR §§ 1.702(b) and 1.703(b)(4). This period of 219 days on Appeal is believed to count as Patent Office Delay pursuant to 35 USC § 154(b)(1)(C)(iii), and is thusly not subtracted from Patent Office delay during the three-years delay period.

Applicant is entitled to an additional adjustment to the patent term based on the USPTO delay between the 14-month date from the date of filing (11/17/2004) and the mailing of the first Office Action (10/05/2007) minus the overlapping days between the three year date (9/17/2006) and the mailing of the first Office Action (10/05/2007).

The USPTO delayed **1052** days between the 14 month date (11/17/2004) and the

mailing date of the first Office Action (10/05/2007), as indicated on PAIR.

The USPTO delayed **1115** days between the 3 year date (09/17/2006) and the date of issuance (10/06/2009).

The total USPTO delay days, as indicated by PAIR, is 1115.

Applicant had 11 delay days as indicated by PAIR.

As such, PAIR indicates the PTA to be 1104.

However:

There were 1052 days between the 14 month date (11/17/2004) and the date of mailing of the first Office Action/Restriction Requirement (10/05/2007). 383 of those days are accounted for above as USPTO delay, due to overlap. As such, there were 732 (1115 - 383) non-overlapping days between the 3 year date (09/17/2006) and the date of issuance (10/06/2009).

Thus, Applicant is entitled to 1052 days due to delays between the 14 month date and the date of the first Office Action, plus an additional 1115 days due to the period beyond the 3 year date of 09/17/2006, minus 383 days of overlap, minus 11 days of Applicant's delay (1052 + 1115 - 383 - 11 = 1773). Thus, Applicant is entitled to an additional 669 days beyond the calculation on PAIR (1104) to account for the delays between the 14 month date (11/17/2004) and the mailing of the first Office Action (10/05/2007).

Applicant was provided with 1115 delay days as indicated by PAIR and is entitled to an additional 669 days. Thus the total adjustment that should have been shown on the face of the patent under 35 USC 154 (b) is **1773** days.

(iii) The patent is not subject to a terminal disclaimer.

(iv) (A) Applicant has included herewith a copy of the print-out from the USPTO's PAIR Patent Term Adjustment page for the above file. Applicant has not verified the USPTO's determination, but accepts it for the purposes of this petition.

**All items required under 37 CFR 1.705 having been provided herein, the Applicant requests that the Patent Term Adjustment be corrected to show an adjustment of 1773 days of patent term extension.**

In addition to the foregoing, and to the extent that the aforementioned 219 days

spent on appeal are attributable to Applicant under 37 CFR § 1.703(b)(4), Applicant alternatively requests that the Patent Term adjustment be corrected to show an adjustment of 1554 days of patent term extension. In this regard, Applicant notes that a patent's term is not extended by time spent on appeal pursuant to 35 USC § 154(b)(1)(B)(ii). However, the time spent on appeal is recovered where the appeal is favorable to Applicant pursuant to 35 USC § 154(b)(1)(C)(iii). 35 USC § 154(b)(1)(C)(iii) states:

Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to . . .

(iii) appellate review by the Board of Patent Appeals and Interferences or by a Federal court in a case in which the patent was issued under a decision in the review reversing an adverse determination of patentability, the term of the patent shall be extended 1 day for each day of the pendency of the proceeding, order, or review, as the case may be.

In the immediate case, Applicant filed an appeal which resulted in the Examiner reopening prosecution. Consequently, Applicant asserts that, at least with respect to the circumstances of the immediate case, 37 CFR § 1.703(b)(4) is not in compliance with the intent of 35 USC § 154(b). However, to the extent that the Office believes that the aforementioned 219 days should be attributed to Applicant delay, Applicant requests that the Patent Term adjustment be corrected to show an adjustment of 1554 days of patent term extension.

**In sum, Applicant requests that the Patent Term Adjustment be corrected to show an adjustment of 1773 days, and in the alternative, requests that the Patent Term Adjustment be corrected to show an adjustment of 1554 days.**

**Request to Hold the Decision on this Petition in Abeyance**

Applicant also requests that the decision on this petition be held in abeyance pending final adjudication of the *Wyeth* case.

Applicant notes that the USPTO has indicated, in other petitions for reconsideration of the patent term adjustment, that it has no regulatory authority to hold such petitions in abeyance. Applicant disagrees on several grounds. The USPTO, as a regulatory agency, is charged with responsibility for decisions regarding the management and administration of its operations. To that end, 35 USC 1(a) states:

**35 U.S.C. 1 Establishment.**

(a) ESTABLISHMENT.— The United States Patent and Trademark Office is established as an agency of the United States, within the Department of Commerce. In carrying out its functions, the United States Patent and Trademark Office shall be subject to the policy direction of the Secretary of Commerce, but otherwise shall retain responsibility for decisions regarding the management and administration of its operations and shall exercise independent control of its budget allocations and expenditures, personnel decisions and processes, procurements, and other administrative and management functions in accordance with this title and applicable provisions of law. Those operations designed to grant and issue patents and those operations which are designed to facilitate the registration of trademarks shall be treated as separate operating units within the Office.

The responsibility referred to in 35 USC 1(a) includes assigning case loads and determining when petitions are reviewed. It is not believed that specific regulations are necessary to govern the details of the day-to-day operation of the USPTO. Note that the MPEP is essentially a compilation of Patent Office procedure, much of which is not expressly provided for under the regulations. As such, even without specific regulatory authority, Applicant contends that it is within the discretion of the USPTO to hold a decision on a petition in abeyance while a controlling legal issue is pending in court.

We further note that the MPEP provides for at least one situation in which a petition may be held in abeyance, notwithstanding the lack of specific regulatory authority. MPEP 724.06 states:

The decision on the petition to expunge should be held in abeyance until the application

is allowed or an Ex parte Quayle action, or a Notice of Abandonment is mailed, at which time the petition will be decided. However, where it is clear that the information was submitted in the wrong application, then the decision on the petition should not be held in abeyance.

The *Wyeth* court has already determined that non-overlapping 3 year dates and 14 month dates must both be taken into account. It makes no sense to force other patentees to file cases under 35 USC §154(b) to preserve their rights. This multiplies litigation defense costs of the Office and unnecessarily increases the patentees' expenses in obtaining their patent rights. A simple public announcement that the Office will hold all patent term requests in abeyance until a final decision on the *Wyeth* appeal – and then decide them all on the basis of that final decision – will allow the USPTO to advance its position in the appeal without harming patentees if the Office is ultimately unsuccessful. Rational workload management considerations within the USPTO and general equitable considerations of fairness to patent owners, both weigh heavily in favor of the Office deferring consideration of any petitions citing the *Wyeth* case until the case has been decided on the appellate level.

Note also that the Administrative Procedure Act prohibits agency action that is “not in accordance with law.” The *Wyeth* court has ruled the Office’s interpretation of §154(d) to be “a construction cannot be squared with the language of §154(b)(1)(B).” Thus the position of the Office on periods of overlap under 154 is “not in accordance with law” within the meaning of the Administrative Procedure Act. *Unless and until* the Office obtains a reversal of that decision, the Office has no legal authority to decide a petition for term adjustment using the statutory construction advanced by the Office in the *Wyeth* case. Simply deciding to issue a decision on this petition while the *Wyeth* case is on appeal using the Office's construction of §154 that it used in the *Wyeth* case would be arbitrary and capricious, given the fact that the Office is on notice that its construction is wrong as a matter of law. The decision would therefore constitute another violation of the Administrative Procedure Act.

Finally, this request specifically impacts a property right that the Applicant is legally entitled to. The due process clause of the U.S. Constitution is violated when the Office decides to deprive patent owners of term under a statutory construction that has been ruled to be contrary to law.

The Office does not have authority under law or the U.S. Constitution to issue a decision denying this request unless it obtains a reversal of the *Wyeth* case. It has the authority to defer decision on this request. Deferring the decision preserves the Office's interest in advocating its construction to a final adjudication while at the same time respecting the property rights of the patent owner in this case. Good cause has been shown for holding this request in abeyance.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: December 4, 2009

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UNITED STATES PATENT AND TRADEMARK OFFICE

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 United States Patent and Trademark Office  
 Address COMBINED/002/2400 PA33515  
 Sd. Inc. 101  
 Alexandria, Virginia 22304-1190  
 www.uspto.gov

APPLICATION NO.	SEQUENCE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663641	10/663641	7507702	S63.2B-11019-US01	1001

 AND TWO OTHERS  
 VIDAS, ARRETT & STEINBERG, P.A.  
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## ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

**Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)**  
 (application filed on or after May 29, 2000)

The Patent Term Adjustment is 1104 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

 Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at (571)-272-4200.

 APPLICANT(s) (Please see PAIR WEB site <http://pair.uspto.gov> for additional applicants):

Traceo Biomedical, Wayzata, MN;



U5007597702B2

(12) **United States Patent**

**Eidenschink**

(10) **Patent No.:** **US 7,597,702 B2**

(45) **Date of Patent:** **Oct. 6, 2009**

(54) **BALLOON ASSEMBLY WITH A TORQUE**

(75) Inventor: **Trace Eidenschink, Wayzata, MN (US)**

(73) Assignee: **Boston Scientific Scimed, Inc., Maple Grove, MN (US)**

(\*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 1104 days.

(21) Appl. No.: **10/663,641**

(22) Filed: **Sep. 17, 2003**

(55) **Prior Publication Data**  
US 2005/0059989 A1 Mar. 17, 2005

(51) Int. Cl.  
**A61M 29/00 (2006.01)**

(52) U.S. Cl. **606/194**

(58) **Field of Classification Search** 604/108.13, 604/103.14, 96/01, 99/04, 104, 305, 106, 604/107, 108, 309, 95/04; 606/191-194  
See application file for complete search history.

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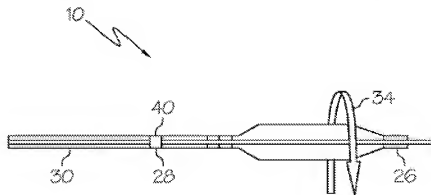
Primary Examiner—Kevin C. Sirmann  
Assistant Examiner—Catherine N. Witzak

(74) Attorney, Agent, or Firm—Vidas, Arrett & Steinkraus, P.A.

(57) **ABSTRACT**

An expandable medical balloon for use in combination with a catheter assembly, the balloon having a torque in a first and second unexpanded state, and to methods of making and using the same.

34 Claims, 2 Drawing Sheets



### Patent Term Adjustments

Patent Term Adjustment (PTA) for Application Number: 10/663,641

Filing or 371(c) Date:	09-17-2003	USPTO Delay (PTO) Delay (days):	1115
Issue Date of Patent:	10-06-2009	Three Years:	-
Pre-Issue Petitions (days):	+0	Applicant Delay (APPL) Delay (days):	11
Post-Issue Petitions (days):	+0	Total PTA (days):	1104
USPTO Adjustment(days):	+0	Explanation Of Calculations	

### Patent Term Adjustment History

Date	Contents Description	PTO(Days)	APPL(Days)
09-16-2009	PTA 36 Months	13	
10-06-2009	Patent Issue Date Used in PTA Calculation		
08-31-2009	Dispatch to FDC	⬆	
08-27-2009	Application Is Considered Ready for Issue	⬆	
08-25-2009	Issue Fee Payment Verified	⬆	
08-25-2009	Issue Fee Payment Received	⬆	
06-17-2009	Mail Notice of Allowance	⬆	
06-16-2009	Document Verification	⬆	
06-16-2009	Notice of Allowance Data Verification Completed	⬆	
06-15-2009	Examiner's Amendment Communication	⬆	
05-30-2009	Date Forwarded to Examiner	⬆	
04-29-2009	Response after Non-Final Action	⬆	
02-06-2009	Mail Non-Final Rejection	50	
02-03-2009	Non-Final Rejection	⬆	
11-21-2008	Appeal Brief Review Complete	⬆	
11-21-2008	Date Forwarded to Examiner	⬆	
11-05-2008	Appeal Brief Filed	⬆	
10-27-2008	Notice -- Defective Appeal Brief	⬆	
08-25-2008	Appeal Brief Review Complete	⬆	
08-25-2008	Date Forwarded to Examiner	⬆	
09-19-2008	Defective / Incomplete Appeal Brief Filed	⬆	
08-18-2008	Appeal Brief Filed	⬆	
07-03-2008	Notice of Appeal Filed		11
07-02-2008	Request for Extension of Time - Granted	⬆	
06-11-2008	Mail Advisory Action (PTOL - 303)	⬆	
06-09-2008	Advisory Action (PTOL-303)	⬆	
05-20-2008	Date Forwarded to Examiner	⬆	
05-15-2008	Amendment after Final Rejection	⬆	
03-21-2008	Mail Final Rejection (PTOL - 326)	⬆	
03-17-2008	Final Rejection		
12-19-2007	New or Additional Drawing Filed		

01-03-2008	Date Forwarded to Examiner	
12-19-2007	Response after Non-Final Action	
10-05-2007	Mail Non-Final Rejection	1052
10-01-2007	Non-Final Rejection	✂
12-11-2003	Information Disclosure Statement considered	✂
03-14-2005	Information Disclosure Statement considered	✂
08-03-2007	Case Docketed to Examiner in GAU	✂
11-09-2006	Case Docketed to Examiner in GAU	✂
05-09-2006	Case Docketed to Examiner in GAU	✂
09-14-2005	Miscellaneous Incoming Letter	✂
03-14-2005	Reference capture on IDS	✂
03-14-2005	Information Disclosure Statement (IDS) Filed	✂
03-14-2005	Information Disclosure Statement (IDS) Filed	✂
07-20-2004	IFW TSS Processing by Tech Center Complete	✂
07-19-2004	Case Docketed to Examiner in GAU	✂
12-11-2003	Information Disclosure Statement (IDS) Filed	✂
12-11-2003	Information Disclosure Statement (IDS) Filed	✂
01-20-2004	Reference capture on IDS	✂
12-10-2003	Application Is Now Complete	✂
12-09-2003	Application Return from OIPE	✂
12-09-2003	Application Return TO OIPE	✂
12-09-2003	Application Dispatched from OIPE	✂
12-09-2003	Application Is Now Complete	✂
12-01-2003	Cleared by OIPE CSR	✂
10-29-2003	IFW Scan & PACR Auto Security Review	✂
09-17-2003	Initial Exam Team mtg	✂

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